

REMARKS

This is in response to the Office Action dated July 28, 2005. Claims 40, 41, 63, 127, 140, and 172-180 are allowed. Claims 45, 54, 57, 59, 62, 68, 70, 78, 80, 81, 88, 123, 141-165, 167 and 168 are rejected. Claims 166 and 169 have been objected to in that they are dependent on a rejected base claim.

Applicants herein amend the Specification to incorporate the sequence of the Italian Priority Document which describes the 130 kDa CAI antigen by partial amino acid and nucleic acid sequence. The contents of this priority document had been incorporated by reference, thus no new matter is added.

Applicants herein amend claims 166 and 169 to incorporate all of the limitations of the base claim. Applicants believe that claims 166 and 169 are now allowable.

The Office Action maintains the rejection of claims 45, 54, 62, 68, 78, 81, 88 and 123 under 35 U.S.C. § 102(b) as allegedly anticipated by Covacci *et al.* (1993) *Proc. Natl. Acad. Sci. USA* 90:5791-5795 ("Covacci"). The Examiner maintains that the claims, as presented, are not entitled to the priority date of the Italian priority document (FI92A/000052). The Examiner appears to rely on a lack of *ipsis verbis* support in the Specification for the description in the Italian priority document. The Italian priority document claims a protein with an apparent molecular weight of 130 kDa as determined by SDS-PAGE comprising a sequence with 228 amino acids. A 228 amino acid sequence would not constitute an entire protein of 130 kDa (the 228 amino acid sequence is calculated to be 24.75 kDa; see attached sequence analysis data), and the priority document states that the protein "comprises" 228 amino acid sequence. As the entire disclosure was incorporated by reference, Applicants herein amend the Specification to include the relevant disclosure from the Italian priority document and amend the Sequence Listing accordingly. Thus, the 228 amino acid sequence appears as SEQ ID NO:25 and the claims are amended accordingly. No new matter is added. The description of the EcoRI site cloning and screening is in the original Italian priority document at pages 6-10 with the sequence shown in **Figure 3B** (described at page 10, lines 16-20) and the convention of showing the coding sequence in uppercase letters and noncoding sequence in lowercase letters is conventional and would be well-understood by one of skill in the art. The patent rules under 37 CFR §§ 1.821-1.825 require the Applicant to

describe the sequences by SEQ ID NO., thus, the added verbiage is included to show the difference between the two sequences (SEQ ID NO:26 versus SEQ ID NO:27). The Applicants earnestly submit that the claims, as presented, are entitled to the priority of the Italian priority document. Therefore, Applicants respectfully urge the Examiner to withdraw the rejection of the claims under 35 U.S.C. § 102(b) over Covacci.

As claims 68, 78, 88, 152, 153, each depend from a claim which, as described above, are entitled to the priority date of the Italian Application, these claims are allowable as well.

Applicants have likewise amended claims 141, 142, 147, 154 and 159 as above to include the wording of the Italian priority document. Thus these claims as well as their respective dependent claims (claims 143-146, 148-151, 155-158 and 160-165) are allowable as well.

The Office Action maintains the rejection of claims 57, 159, and includes dependent claims 164 and 165 (which were previously inadvertently omitted from the previous rejection) under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,403,924 to Cover *et al.* ("Cover I") and Dunn *et al.* (1992) *Infect. Immun.* 60:1946-1951, in view of Hirschl *et al.* (In *HELICOBACTER PYLORI*, GASTRITIS AND PEPTIC ULCER, (Ed.) Malfertheiner *et al.*, Springer-Verlag, Berlin Heidelberg, pp. 141-146, 1990)("Hirschl"). Applicants herein amend claim 57 to include the feature that the second polypeptide is purified. Support for the amendment may be found, for example on page 3 lines 37-39 through page 4 line 1. The Specification teaches what is meant by "purified" at page 16, lines 19-29. No new matter is added. Applicants respectfully submit that the art does not teach or suggest a purified second polypeptide used in conjunction with a first purified polypeptide. Hirschl teaches that antigens that are only partially purified (note that the "partially purified" antigens of Hirschl are crude cell lysates subjected to centrifugation and acid glycine extraction) are useful and that highly purified antigens are disfavored. As the Applicants teach purified proteins (at least 75% free of other molecules of the same type as taught at page 16, lines 19-29), Applicants distinguish over the hypothetical combination of Cover I, Dunn and Hirschl. Applicants respectfully request withdrawal of the rejection of claim 57 under 35 U.S.C. § 103(a). As claims 59, 164 and 165 depend from claim 57, it is earnestly submitted that these claims are allowable as well.

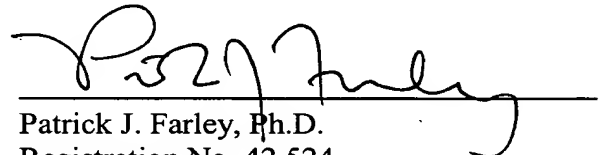
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PATENT

The Office Action maintains the rejection of claims 70, 80, 167 and 168 under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,054,132 to Cover *et al.* ("Cover II") and Cover I, in view of Hirschl. Applicants herein amend claim 70 to include the feature that the second polypeptide is purified. Support for the amendment may be found, for example on page 3 lines 37-39 through page 4 line 1. The Specification teaches what is meant by "purified" at page 16, lines 19-29. No new matter is added. Applicants respectfully submit that the art does not teach or suggest a purified second polypeptide used in conjunction with a first purified polypeptide. Hirschl teaches that antigens that are only partially purified (note that the "partially purified" antigens of Hirschl are crude cell lysates subjected to centrifugation and acid glycine extraction) are useful and that highly purified antigens are disfavored. As the Applicants teach purified proteins (at least 75% free of other molecules of the same type as taught at page 16, lines 19-29), Applicants distinguish over the hypothetical combination of Cover I, Cover II and Hirschl. Applicants respectfully request withdrawal of the rejection of claim 70 under 35 U.S.C. § 103(a). As claims 80, 167 and 168 depend from claim 70, it is earnestly submitted that these claims are allowable as well.

Applicants respectfully submit that all pending claims are in condition for allowance, which action is respectfully requested.

Respectfully submitted,



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